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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,164	CHRISTIE ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-19* is/are pending in the application.

4a) Of the above claim(s) *12 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,13-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/26/06*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group III (claims 10-11, 13-17 and 19, method of treatment with antibodies, species: Ab#13) in the reply filed on 12/12/07 is acknowledged.

Claims 1-9 have been canceled previously. Claims 12, 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim rejections-35 USC § 112, written description

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2a. Claims 10-11, 13-17, 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reducing the incidence and severity of the relapse phase in multiple sclerosis (MS) comprising administering an effective amount of an antibody to IL-17 to a subject suffering from multiple sclerosis, wherein the antibody administered is Ab#13 mIgG1 antibody, does not reasonably provide enablement for a method for treating MS comprising administering a therapeutically effective amount of an inhibitor of IL-17 activity to a patient in need thereof as recited in claim 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification delimits the instant method to administering antibody Ab#13 mIgG1 (see page 26, lines 21-25), however, claim 10, recites a method for treating MS comprising

administering a therapeutically effective amount of an inhibitor of IL-17 activity to a patient in need thereof.

With respect to the claims, as recited, what is claimed in the instant invention broadly encompasses a method of administering "all" inhibitors of IL-17 activity. While the specification discloses that "suitable inhibitors" include but are not limited to, a synthetic functional fragment of the IL-17 receptor that binds to IL-17 and interferes with binding to the native IL-17 receptor, an antibody that binds to IL-17 or to the IL-17 receptor and interferes with IL-17 receptor-ligand interaction, an antisense nucleic acid molecule that specifically hybridizes to mRNA encoding IL-17 or the IL-17 receptor or a small molecule or other drug which inhibits the activity of IL-17 or its receptor (see page 4, lines 18-23) and that the term "IL-17 activity" refers to the spectrum of activity understood in the art for IL-17 for example, the induction of secretion of IL-6 or IL-8 from fibroblasts by IL-17 (Yao *et al.*, 1995, Journal of Immunology, 155,5483-5486) (see page 4, lines 4-6) and this is the biological property which the administered compound is expected to exhibit, the specification is non-enabling for the unlimited number of compositions comprising "an inhibitor of IL-17 activity", and which are encompassed by the scope of the claims. Furthermore, the specification (page 4, lines 24-31) recites:

Inhibitors of IL-17 activity are well known in the art as are methods of identifying and producing such inhibitors. Examples include, IL-17R:Fc fusion proteins (Lubberts *et al.*, J.Immunol. 2001,167, 1004-1013) and neutralising antibodies (Chung *et al.*, 2002, J.Exp.Med., 195, 1471-1478; Ferretti, 2003, Journal of Immunology, 170, 2106-2112). Agents that may be suitable inhibitors can be selected from a wide variety of candidate agents. Examples of candidate agents include but are not limited to, nucleic acids *(e.g.* DNA

and RNA), carbohydrates, lipids, proteins, polypeptides, peptides, peptidomimetics, small molecules and other drugs.

Claim 10, for example, is a single means claim (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: "A single means claim, i.e. where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph." (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). Since no material limitations for the inhibitor of IL-17 activity have been recited in claim 10 and only a biological activity has been recited, the claim encompasses every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. Therefore, not only proteins, such as IL-17 antibodies and IL-17 receptor antibodies but antisense nucleic acid molecule that specifically hybridizes to mRNA encoding IL-17 or the IL-17 receptor or a small molecule or other drug which inhibits the activity of IL-17 or its receptor, are encompassed by the scope of the claim. The claimed invention encompasses a method of administering compositions not envisioned or described in the specification, and neither does the specification disclose how these claimed compositions can be distinguished from each other. The specification only enables a method for reducing the incidence and severity of the relapse phase in multiple sclerosis (MS) comprising administering an effective amount of an antibody to IL-17 to a subject suffering from multiple sclerosis, wherein the antibody administered is Ab#13 mIgG1 antibody, the antibody having specific characteristics and properties. These properties may differ structurally, chemically and

physically from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which other IL-6 antagonists to be administered are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little, thereby rendering the results of the methods taught in the specification unpredictable (see pages 26-30). Therefore, it would require undue experimentation to determine which inhibitors of IL-17 activity to be administered in the claimed method would be encompassed by the scope of the claims. The disclosure of the one antibody, Ab#13 mIgG1, is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims, which encompass every and all IL-6 antagonist. In In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without

difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Furthermore, the amount of embodiments corresponding to the desirable compositions in the claimed method, may be innumerable, and the enabled embodiments amount to only one. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe treatment of MS with an inhibitor of IL-17 activity other than a method for reducing the incidence and severity of the relapse phase in multiple sclerosis (MS) comprising administering an effective amount of an antibody to IL-17 to a subject suffering from multiple sclerosis, wherein the antibody administered is Ab#13 mIgG1 antibody, and since it is deemed to constitute undue experimentation to determine all the other IL-17 inhibitors to be used in the claimed method, the disclosure is not commensurate with the scope of the claims. It is suggested that by employing conventional claim language, the claims be amended to include the specific antibody supported by the instant specification in the claimed method.

The following reference is cited herein to illustrate the state of the art with respect to antibodies:

Chuntharapai et al. (1997) note that the vast majority of antibodies are not antagonistic and that antibodies have to be screened to determine their ability to bind to human neutrophils (see page 21, second para). The reference also discloses that blocking activities of monoclonals

when compared show disparate blocking on ligand binding and inhibition of ligand binding or no inhibition at all (see page 24, last 2 lines; page 25).

Claim rejections-35 U.S.C. 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 10-11, 13-17, 19, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite for several reasons.

Claim 10, lines 2-3, is vague and indefinite because it recites "an inhibitor of IL-17 activity". The metes and bounds of the claim are unclear because it is unclear which of the numerous IL-17 activities as to be inhibited in the instant method. Furthermore, the claim is unclear because the metes and bounds of the term "inhibitor" are unclear. Inhibitor encompasses "antibodies to IL-17 or IL-17 receptor, antisense nucleic acids to mRNA encoding IL-17 or IL-17 receptor or peptides and drugs that bind to the receptor". It is suggested that to obviate this rejection, the claim be amended to recite the specific IL-17 inhibitor i.e. antibody Ab#13 mIgG1, for which there is a basis in the instant specification.

Claim 10 is vague and indefinite because it is a method claim but fails to recite method steps in the claim.

Claim 16 is vague and indefinite because the metes and bounds of the term "effector molecule" are unclear. It is suggested that to obviate this rejection the claim be amended to recite the "effector molecules" for which there is a basis in the instant specification.

Claim 19 is rejected as vague and indefinite because the metes and bounds of the term "therapeutically active compounds" are unclear. For what are the compounds therapeutically active? It is suggested that to obviate this rejection the claim be amended to recite the "therapeutically active compounds" for which there is a basis in the instant specification.

Claims 11, 13-15, 17, are rejected as vague and indefinite insofar as they depend on the above rejected claim for their limitations.

Conclusion

No claim is allowed.

Claims 10-11, 13-17, 19, are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646